UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

MAY - 1 2012

VIA HAND DELIVERY

Headquarters Hearing Clerk (1900L)
Office of Administrative Law Judges
United States Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: Complainant's Reply Brief

Docket No. TSCA-HQ-2010-5022

Dear Madam:

Enclosed please find an original and two (2) copies of the Complainant's Reply Brief, in the above matter.

Please file the original Complainant's Reply Brief and return one date-stamped copy to Complainant.

Thank you for your attention to this matter.

Sincerely,

for Mark A.R. Chalfant
Counsel for Complainant

Enclosure

cc: John J. McAleese, III, Morgan Lewis & Bockius LLP (via email and UPS Next Day)
Ronald J. Tenpas, Morgan Lewis & Bockius LLP (via email and UPS Next Day)
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The Honorable Susan L. Biro, U.S. EPA Office of Administrative Law Judges (hand delivery only)

CERTIFICATE OF SERVICE

I certify that the foregoing *Complainant's Reply Brief* in Docket No. TSCA-HQ-2010-5022, dated May 1, 2012, was sent this day in the following manner to the addresses listed below:

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UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

IN THE MATTER OF:	)	
	)	
	)	
Elementis Chromium Inc.,	)	Docket No. TSCA-HQ-2010-5022
f/k/a Elementis Chromium, LP	)	
	)	
Respondent.	)	
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COMPLAINANT'S REPLY BRIEF

Complainant, the United States Environmental Protection Agency (Complainant, EPA or the Agency) respectfully submits its Reply Brief pursuant to the Presiding Officer's Post-Hearing Scheduling Order.

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I. INTRODUCTION

In its Initial Post-Hearing Brief, Respondent Elementis Chromium Inc. (Elementis) concedes the Environmental Protection Agency's (EPA's) prima facie case of liability under section 8(e) of the Toxic Substances Control Act against Elementis, which constitutes an unlawful act under section 15(3)(B) and subjects the company to the assessment of civil penalties for each day of the violation, pursuant to section 16.[1] (Resp't Initial Post-Hearing Brief at 2.) Having conceded EPA's prima facie case, the disposition of this case turns on whether Respondent has met its burden to establish the statutory affirmative defense available to it under section 8(e). Elementis has the burden to establish its defense by a preponderance of the evidence. See 40 C.F.R. § 22.24(a); see also Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Arg. at 11; In re Methyl Tertiary Butyl Ether Products Liab. Litig., 559 F. Supp. 2d at 424, 435 (S.D.N.Y. 2008).

Elementis is silent in its Initial Post-Hearing Brief about the burden it bears to establish its statutory affirmative defense, and how the evidence, in its view, meets that burden. (See generally, Resp't Initial Post-Hearing Brief.) Rather, Elementis states that it "did not feel the need" to provide the industry-commissioned Final Four Plant Report to the EPA Administrator. Id. at 11. Whether or not Elementis felt the need to submit the Final Four Plant Report to the Agency, the record is clear in three respects: (1) the Final Four Plant Report contains new information about the risk of lung cancer mortality from hexavalent chromium under long-term, low-intensity exposure conditions, which was required to be reported to the Administrator

[1] In the opening paragraph to its Initial Post-Hearing Brief, Respondent mistakenly cites a non-existent statutory provision in TSCA. (Resp't Initial Post-Hearing Brief at 1.) Specifically, Respondent cites to section 15(c) of TSCA, 15 U.S.C. § 2614(c). The correct citation is section 15(3)(B). (See Complaint and Notice of Opportunity for Hearing, ¶ 51 citing TSCA section 15(3)(B), 15 U.S.C. § 2614(3)(B); Compl't Initial Post-Hearing Brief at 6.)

pursuant to section 8(e); (2) the Administrator had not been adequately informed of the information contained in the Final Four Plant Report; and (3) Elementis did not have actual knowledge that the Administrator had been adequately informed of the information in the Final Four Plant Report at the time it obtained the report in 2002. Therefore, the record shows that Respondent is liable as a matter of law for its continuing violation of section 8(e) of TSCA and should be assessed a civil penalty of $2,338,000.

II. ARGUMENT

A. Elementis Has Not Met Its Burden of Proof to Establish its Statutory Affirmative Defense Under TSCA Section 8(e).

Respondent has the burden to prove its statutory affirmative defense under TSCA section 8(e) by a preponderance of the evidence. (Order on Compl't Mot. for Acc. Dec. and Resp't Req. for Oral Arg. at 17.) "Preponderance of the evidence" is that degree of proof which is more likely than not. In Re: Morton I. Friedman and Schmitt Constr. Co., 11 E.A.D. 302 (EAB 2004); In Re: Echevvarria, 5 E.A.D. 626, 638 (EAB 1994) ("In essence, the preponderance of the evidence standard means that a fact finder should believe that [the fact finder's] factual conclusion is more likely than not."). Thus, Respondent has the burden of proving that it is more likely than not that it had actual knowledge that the EPA Administrator had been adequately informed of the information in the Final Four Plant Report which reasonably supports the conclusion that hexavalent chromium presents a substantial risk of injury to human health.

1. Respondent Wrongly Argues that Elementis Was Not Required To Inform EPA of the Final Four Plant Report Because the Report Contains New Substantial Risk Information.

In its Initial Post-Hearing Brief, Respondent posits that Elementis was not required to inform the EPA Administrator of the Final Four Plant Report because Elementis had actual

knowledge that the Administrator had been adequately informed of the information contained in the report. (Resp't Initial Post-Hearing Brief at 6, 11.) In describing its position, Respondent asserts that the Final Four Plant Report adds "nothing new" to the scientific knowledge base about the risk of lung cancer mortality from hexavalent chromium exposure. Id. at 2, 3, 49. However, the record shows that the Final Four Plant Report contains new information about the risk of lung cancer mortality from hexavalent chromium exposure under long-term, low-intensity exposure conditions. Thus, Respondent wrongly concludes that it was not required to inform the Administrator of the Final Four Plant Report.

Respondent mischaracterizes the basis for EPA's TSCA section 8(e) claim against Elementis in its Initial Post-Hearing Brief. In particular, Respondent incorrectly asserts that the "sole basis" on which EPA maintains its claim is differences in the intensity of exposure between the Gibb et al. and Final Four Plant Report studies. (Resp't Initial Post-Hearing Brief at 4.) Contrary to Respondent's assertion, EPA's claim is based on differences in the duration and the intensity of exposure. (Compl't Initial Post-Hearing Brief at 31-36.) Moreover, Respondent dismisses the relevance of these two factors, even though both are directly related to cumulative exposure.[2] (Cf. Resp't Initial Post-Hearing Brief at 4 and Compl't Initial Post-Hearing Brief at 31.) Exposure intensity or concentration (amount) multiplied by the duration of exposure (time component) equals cumulative exposure. (Compl't Initial Post-Hearing Brief at 31 (equation for calculating cumulative exposure).) As a working hypothesis, epidemiologists assume that different combinations of intensity and duration of exposure resulting in the same cumulative

[2] In its Initial Post-Hearing Brief, Respondent asserts that the two components of cumulative exposure — intensity and duration of exposure— are "irrelevant" to the risk of developing lung cancer in the Final Four Plant Report. (See Resp't Initial Post-Hearing Brief at 4-5.) In an inappropriate analogy, Respondent discusses using hair color to measure vision, which is clearly unrelated. See id. In contrast, intensity and duration of exposure are directly related to cumulative exposure, the metric used to evaluate lung cancer mortality risk in the Final Four Plant Report. (Compl't Initial Post-Hearing Brief at 31.)

exposure present the same health risk. (Tr. at 153-54 (Cooper).) But only actual data can confirm this assumption. See id. at 154. Therefore, the intensity and duration of exposure are scientifically relevant and important to EPA and other agencies for risk assessment and other purposes. Id. at 153. Consequently, Respondent wrongly dismisses the relevance of these factors.

The record shows that the Gibb et al. and the Final Four Plant Report studies report elevated lung cancer mortality risk at comparable cumulative exposure levels. (Compl't Initial Post-Hearing Brief at 32.) As Respondent acknowledges in its Initial Post-Hearing Brief, comparable cumulative exposure levels can be based on different combinations of intensity and duration of exposure. (Resp't Initial Post-Hearing Brief at 43; see also id. at 32-33.) The cumulative exposure in the Final Four Plant Report's overall cohort is based on a longer duration of exposure than the Gibb et al. study's overall cohort. (Compl't Initial Post-Hearing Brief at 33.) Thus, the Final Four Plant Report's overall cohort necessarily must have a lower intensity of exposure than the Gibb et al. study's overall cohort to have the same cumulative exposure over a longer period. Id. Consequently, the Final Four Plant Report contains new information about the risk of lung cancer from hexavalent chromium exposure because the cumulative exposures in the Gibb et al. and Final Four Plant Report studies represent different exposure conditions in the overall cohorts.

Elementis advances two arguments in support of its position that the Final Four Plant Report contains "nothing new" about lung cancer mortality risk from hexavalent chromium exposure. First, Respondent argues that the only information in the Final Four Plant Report which meets TSCA section 8(e)'s reporting threshold is the report's finding of increased risk in chromate production workers exposed to "high" cumulative levels of hexavalent chromium.

(Resp't Initial Post-Hearing Brief at 2.) Second, Respondent argues that the Gibb et al. study, published prior to the Final Four Plant Report, found not only elevated risk at "high" cumulative exposure levels, but at statistically significant, lower cumulative exposure levels than the Final Four Plant Report. Id. Based on these arguments, Respondent asserts that it had actual knowledge that the EPA Administrator had been adequately informed of the information in the Final Four Plant Report. Id. The record does not support Respondent's arguments.[3]

Before refuting Respondent's arguments for its position that the Final Four Plant Report does not contain new substantial risk information, Complainant wishes to ensure that the record is clear about hexavalent chromium exposure levels in modern chromate production plants. In filings before this Court, Respondent has perpetuated the misconception that the Final Four Plant Report concerns the extent of lung cancer mortality risk to workers exposed to "high" cumulative exposure levels. (See Resp't Response to Compl't Mot. for Acc. Dec. at 2-3, 12, 16; Resp't Pre-Hearing Brief at 9; Resp't Initial Post-Hearing Brief at 1-2, 10, 17, 19, 27.) Respondent implies that the underlying average exposure concentrations are high. See id. In fact, exposure levels in

[3] In addition to these arguments, Respondent contends that EPA's fellow agency, the Occupational Safety and Health Administration (OSHA), determined that the Final Four Plant Report was not valuable for quantifying risk at low exposure levels as part of its rulemaking to set a new standard for occupational exposure to hexavalent chromium. (Resp't Initial Post-Hearing Brief at 49.) To support its assertion, Respondent relies upon a statement in OSHA's 2006 Final Rule, which reads, "the Agency [OSHA] does not believe that quantitative analyses of these studies would provide additional information on risk from low exposures to Cr(VI)." CX 76 at 81 [2006 OSHA Final Rule (71 Fed. Reg. 10,169)].

Respondent's reliance upon this statement is misplaced because the Final Four Plant Report is not one of the epidemiological studies which OSHA is referring to in its statement. (Cf. Resp't Pre-Hearing Brief at 4-5, Resp't Initial Post-Hearing Brief at 49, and Tr. at 1123-27 (Edens).) Its reliance is also misplaced because technological and economic feasibility constraints rendered the Final Four Plant Report immaterial to OSHA's rulemaking by the time OSHA learned of the report late in the rulemaking. (Tr. at 1106-07, 1112-13, 1119-20 (Edens); see also CX 76 at 3-4 [2006 OSHA Final Rule].) Finally, Respondent's reliance is curious given that Elementis never disclosed the Final Four Plant Report to OSHA during its rulemaking. (Tr. at 1151-52, 1161-62 (Edens)).

modern plants are not high by historical standards because modern plants' average exposure concentrations are five to ten times lower than older plants. That is the primary reason the study for the Final Four Plant Report was conducted and why it clearly differs from the majority of prior studies. (Tr. at 1090 (Speizer); see also CX 1 at 18 [FFPR] ("The last several years have witnessed growing interest in the possible health effects of chromium compounds at lower exposure levels." (emphasis added)); CX 3 at 51 [FFPR Study Protocol Peer Review Comments of Dr. Harvey Checkoway] ("[T]he results of this study could shed light on risks related to much lower levels that typify modern processes." (emphasis added)).)

Respondent's first argument that the only information in the Final Four Plant Report which meets TSCA section 8(e)'s reporting threshold is the report's finding of increased risk in chromate production workers exposed to "high" cumulative levels of hexavalent chromium is wrong. As discussed in Complainant's Initial Post-Hearing Brief, Respondent's reading of the Final Four Plant Report narrowly focuses on the finding of elevated risk in the study cohort's highest exposure group, and then compares that finding and its supporting data to the level of risk in the cohort's remaining three lower exposure groups. (Resp't Initial Post-Hearing Brief at 8.) Respondent's reliance on piecemeal findings and data for individual exposure groups to the exclusion of all of the data for the overall cohort is not consistent with the purpose of the study. (Tr. at 544-46 (Speizer).) As explained at hearing by Dr. Speizer, one of the nation's preeminent epidemiologists, the Final Four Plant Report study was designed to examine the risk of lung cancer mortality from hexavalent chromium exposure in the total study population. Id. at 544. Dr. Speizer also explained that arbitrarily "picking individual [exposure] groups and looking at them separately" where an epidemiological study such as the Final Four Plant Report involves quartiles is tantamount to "throwing away 75 percent of the data" because "you're only looking

at a subsegment of what the study is designed to measure." Id. at 544. In drawing upon his extensive experience in the field of epidemiology, Dr. Speizer additionally explained that "the fact that individual [exposure] groups show or don't show differences is essentially irrelevant" in light of the study's hypothesis that "the risk would be null" at lower cumulative exposure levels (i.e., the study investigators predicted they would find "no effect"). Id. at 545, 549. Dr. Speizer concluded, "I think the focus on the individual [exposure] groups is simply misusing the data completely . . . . So that's [an] inappropriate use of a subsegment of the data. The fact that the highest group turned out to be significant [is] gratuitous. The trend is mostly what's in all of the data and that's what we should be using . . . ." Id. at 545-46; see also Tr. at 237 (Cooper) ("It's the pattern that you really want to be evaluating within your data."). Thus, Respondent's first argument fails because the trend in the overall study cohort is the most appropriate use of all of the data in an epidemiological study as Dr. Speizer established in his testimony.

Elementis's second argument that the Gibb et al. study found not only elevated risk at "high" cumulative exposure levels, but at statistically significant, lower cumulative exposure levels than the subsequent Final Four Plant Report is only partially correct. In expanding upon this argument, Respondent states that the Final Four Plant Report shows no increased risk "[f]or the lowest three quartiles." (Resp't Initial Post-Hearing Brief at 9.) Respondent correctly states that the Gibb et al. study found increased risk at statistically significant, lower cumulative exposure levels than the Final Four Plant Report. However, this argument squarely pertains to a piecemeal individual exposure group, namely, the highest exposure group. Even Respondent's expert, Dr. Mundt, acknowledged at hearing the arbitrariness of separating a study cohort into individual exposure groups, which involves choosing the number of exposure groups and the exposure levels at which to divide the groups. (See Tr. at 737 (Mundt) ("It's arbitrary."), 755

("[W]e've got three arbitrary categories . . .").) Moreover, Respondent is not correct in elevating the importance of statistical significance over practical significance in interpreting a study's findings because statistical significance provides only limited information in the evaluation of epidemiological data. (Tr. at 263-64 (Cooper) ("What you look for is the pattern of results across exposures, rather than the statistical significance of any individual estimate from one particular group within a study.")) Even if statistical significance were relevant, neither TSCA section 8(e) nor EPA's section 8(e) guidance contemplates a statistical significance test for determining the reportability of substantial risk information. See generally, 15 U.S.C. § 2607(e); CX 17 [1978 EPA 8(e) Guidance]; CX 21 [1991 EPA 8(e) Reporting Guide]; see also REFERENCE GUIDE ON STATISTICS, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 292 (Federal Judicial Center & National Research Council of the National Academies eds., The National Academies Press, 3rd ed. 2011), available at *http://www.fjc.gov/public/pdf.nsf/lookup/SciMan3D01.pdf/$file/SciMan3D01.pdf.* ("Statistical significance does not necessarily establish practical significance"). Thus, Respondent's second argument again fails because the trend in the overall cohort is the most appropriate use of all of the data. In summary, neither of Respondent's arguments has a bearing on whether the Final Four Plant Report contains new substantial risk information because both are based on piecemeal findings and data for individual exposure groups rather than the entire study population. Finally, even if these arguments were correct, that does not necessarily mean that the information about lung cancer mortality risk under different underlying exposure conditions in the Final Four Plant Report is not new.

Respondent may argue on surrebuttal that, even if Elementis were to concede that the trend in the overall study cohort is more appropriate from an epidemiological perspective in

interpreting a study, the Final Four Plant Report still does not contain new information because both the Gibb et al. and Final Four Plant Report studies show a comparable trend of increasing risk with increasing cumulative exposure. But Respondent's anticipated argument would not withstand scrutiny because there are relevant and important differences in the data underlying the two trends — the new substantial risk information at the heart of this case. When asked about the comparability of the trends in these studies, Dr. Speizer stated that these studies involve "different populations" highlighting differences in the duration of exposure due to the high percentage of short-term workers in the Gibb et al. study cohort. (Tr. at 546-48 (Speizer).) Specifically, he observed that half of the Gibb et al. study cohort worked less than five months. Id. at 547 ("50 percent"); see also CX 62 at 6 (Table II) (Total group median work years = 0.39 (39% of 1 year = 4.68 months)). In contrast, Dr. Speizer noted that all of the members of the Final Four Plant Report cohort worked for at least one year. Id. at 548; see also CX 1 at 43 [FFPR].

Respondent's own experts have acknowledged key differences in the studies' cohorts with respect to the duration of exposure. Dr. Mundt, Respondent's expert and the principal author of the Final Four Plant Report, states in the report, "Excluded from this study were . . . employees with less than one year total employment in the modern plants." CX 1 at 43 [FFPR]. In contrast, Dr. Gibb, Respondent's other expert and the lead author of the Gibb et al. study, states in his report, "It was also decided to include workers in the current study who worked less than 90 days . . . ." CX 62 at 2 [Gibb (2000)]. At hearing, Dr. Gibb freely volunteered that he intentionally included workers who were employed less than 90 days in the Gibb et al. study cohort because he "wanted to look at what is the risk to people who are exposed less than 90 days. So I included people less than 90 days in the study." (Tr. at 1030-31 (Gibb).) As the

chromate production industry's own critique of the Gibb et al. study reveals, 40 percent of the Gibb et al. study cohort worked less than 90 days and seventy-five percent worked less than two years. CX 65 at 4, 5 [2002 Chrome Coalition Critique of Gibb et al. Study] ("The cohort is characterized by a very large number of short-term workers."). This critique defines "short-term" as "work[ing] for less than one year." Id. at 5. In sum, the Gibb et al. and the Modern Four Plant Report studies on their face show substantial differences in the duration of exposure in the studies' respective overall cohorts.

In its Initial Post-Hearing Brief, Respondent unsuccessfully tries to deflect EPA's position that the studies' respective cohorts are fundamentally different by relying upon Dr. Mundt's testimony that "[y]ou've got the full spectrum of relatively short-term to very long-term workers" in the Final Four Plant Report. (Resp't Initial Post-Hearing Brief at 18, citing Tr. at 724 (Mundt) (emphasis added).) At hearing, Dr. Mundt hedged his statement with the qualifier, "relatively," in an apparent concession to the fact that the Final Four Plant Report excludes short-term workers who had worked less than one year. Even by Drs. Mundt and Gibb's statements in the reports themselves as well as their testimony at hearing, short-term means at least one year for members of the Final Four Plant Report cohort and at least one to 90 days for members of the Gibb et al. study cohort. Cf. CX 1 at 43 [FFPR] and CX 62 at 2 [Gibb (2000)]; Tr. at 1030-31 (Gibb). Although the Final Four Plant Report cohort may contain some "relatively" shorter-term workers (1 year + some unspecified period), all members of the cohort worked at least one year and none worked for as short a period (< 1 year) as a substantial percentage of the Gibb et al. study cohort. Thus, Respondent's reliance upon Dr. Mundt's qualified statement at hearing does not save Respondent's argument.

Respondent also attempts to deflect EPA's position by claiming in its Initial Post-Hearing Brief that "the term of employment . . . is not uniformly 'long-term,' [in the Final Four Plant Report] as EPA has incorrectly stated, but rather varies greatly, as would be expected." (Resp't Initial Post-Hearing Brief at 16 (emphasis added).) In invoking language purportedly found in Complainant's Initial Post-Hearing Brief, Respondent references no specific page in the brief. Id. In fact, EPA never uses the term "uniformly" in its Initial Post-Hearing Brief. (See generally, Compl't Initial Post-Hearing Brief.) Moreover, in an effort to prove that the duration of exposure varies substantially in the Final Four Plant Report cohort, Respondent focuses on a single figure in the report (Figure 24), which presents information about the term of employment for a small subset of the overall cohort to the exclusion of another table in the report which presents duration of exposure by plant for the overall cohort. Cf. CX 1 at 147 [FFPR] (Figure 24 (Year of Hire, Separation and Death—25 U.S. Lung Cancer Cases)) and id. at 113 (Table 9 (Duration of Exposure for Combined 1,518-Member Cohort by Plant)). As Complainant's Initial Post-Hearing Brief states, the Gibb et al. study reports the average (mean) duration of exposure for the overall cohort to be 3.1 years with a median duration of less than five months; in contrast, the Final Four Plant Report reports the average duration of exposure for the overall cohort to be 8 to 12 years. (Compl't Initial Post-Hearing Brief at 31-32.) Although the duration of exposure varies among members of the Final Four Plant Report cohort, it is undisputed that all of the workers in the Final Four Plant Report cohort were employed for at least one year while over half of the workers in the Gibb et al. study cohort were employed less than one year. CX 1 at 43 [FFPR]; CX 62 at 2 [Gibb (2000)]; Tr. at 1030-31 (Gibb). This information clearly demonstrates that the Final Four Plant Report evaluated longer term and lower intensity exposures in the overall study cohort than the Gibb et al. study.

Finally, Respondent argues as a matter of policy that EPA's approach for determining the reportability of the Final Four Plant Report sets an unreasonable standard for complying with TSCA section 8(e) because EPA allegedly relied upon "information" that Elementis never possessed to compare the Gibb et al. and Final Four Plant Report studies. (See Resp't Initial Post-Hearing Brief at 35.) Specifically, Respondent contends it is not possible to draw conclusions about exposure conditions from the Final Four Plant Report given that the report obtained cumulative exposures using job exposure matrices for individual employees, and therefore, EPA had to resort to "after-the-fact calculations and manipulations." See id. at 5, 30-31, 35. Contrary to Respondent's contention, EPA evaluated the reportability of the Final Four Plant Report based on averages (means), a commonly used descriptive statistic. See REFERENCE GUIDE ON STATISTICS at 289, 292 (Definitions of "descriptive statistic" and "mean"). Despite the investigators' use of job exposure matrices to generate cumulative exposure estimates for individual employees in the Final Four Plant Report, a basic approximation of the exposure conditions in both the Gibb et al. and Final Four Plant Report studies' overall cohorts may be obtained using average duration values directly reported in these studies. CX 62 at 6 (Table II) [Gibb (2000)]; CX 1 at 113 (Table 9) [FFPR]. Thus, EPA's approach for determining reportability relying upon a commonly accepted descriptive statistic does not set an unreasonable standard for complying with TSCA section 8(e).

2. Respondent Wrongly Contends that EPA Was Adequately Informed of the Substantial Risk Information in the Final Four Plant Report; Therefore, Elementis Could Not Have Had Actual Knowledge.

Respondent's contention that the EPA Administrator was adequately informed of the information in the Final Four Plant Report, and that it had actual knowledge that the Administrator had been adequately informed of the information in the Final Four Plant Report at

the time Elementis obtained the report in 2002, is mistaken. Respondent wrongly contends that it had actual knowledge that the EPA Administrator had been adequately informed of the information in the Final Four Plant Report. (Resp't Initial Post-Hearing Brief at 1.) As discussed in the preceding section, the record shows that the EPA Administrator had not been adequately informed of the information in the Final Four Plant Report. Having established that EPA had not been adequately informed of the information in the Final Four Plant Report, it follows logically and inexorably that Respondent could not have had actual knowledge that the EPA Administrator had been adequately informed of the information in the Final Four Plant Report at the time Respondent obtained the report in 2002. Thus, Respondent errs in contending that it had actual knowledge that EPA had been adequately informed of the information in the Final Four Plant Report.

B. Elementis Has Not Shown Reason Why the Proposed Civil Penalty Is Not Appropriate In Light of the Statutory Penalty Criteria.

Respondent asserts that the proposed civil penalty is "excessive and unwarranted" and that further consideration should have been given to the facts and circumstances of this matter "as justice may require." (Resp't Initial Post-Hearing Brief at 48.) Complainant disagrees with Respondent's assertion. The record shows that the proposed penalty of $2,338,000 was calculated after full consideration of the statutory penalty criteria and applicable penalty policies, as well as the specific facts and circumstances of this case. Thus, Elementis has not shown reason why the proposed penalty is not appropriate.

In its Initial Post-hearing Brief, Respondent alleges that EPA's Enforcement Response Policy for Reporting and Recordkeeping Rules and Requirements for TSCA Sections 8, 12, and 13 ("TSCA ERP") "does not allow for consideration of differing circumstances in actions involving violations of TSCA Section 8(e), and therefore should not be followed in this matter."

Id. Specifically, Respondent argues that the proposed penalty calculation fails to consider that 1) the information in the Final Four Plant Report "is of so little consequence that not a single regulatory action has resulted or is contemplated based on the information...," 2) Respondent's failure to report was based on a "good-faith" belief that the information was not reportable, and 3) that Respondent's violation was not "significant" or "obvious." Id. at 48-49.

With respect to Respondent's first argument, as has been discussed at length throughout this proceeding, Complainant disagrees with Respondent's assertions that the Final Four Plant Report does not "add anything to the knowledge base about the risks associated with exposure to hexavalent chromium" and that "the actual value of the Final Four Plant Report to EPA is clearly not significant." See id. at 49. It is not up to a respondent to determine what value the Agency attaches to particular information; however, in calculating a proposed penalty for a TSCA section 8(e) violation, the Agency does consider both the impact of the violation on the Agency and the type of information involved. As discussed both at hearing and in Complainant's Initial Post-Hearing Brief, the TSCA ERP sets forth two alternative formulas for calculating the penalty for a TSCA section 8(e) violation: one for situations where the Agency has made a determination that the violation disrupted the Agency's ability to address situations involving potential imminent hazards, substantial endangerments, or unreasonable risks, and a second for all other TSCA section 8(e) violations. CX 103 at 12-13 [1999 TSCA ERP], Compl't Initial Post-Hearing Brief at 52, Tr. at 624 (Ellis). In this case, as noted by Respondent, the Agency has not yet had the opportunity to use the information in the Final Four Plant Report; therefore, the proposed penalty was calculated using the second formula. This resulted in a significantly lower penalty than had the Agency made the determination that its ability to address risks had been disrupted. (See Tr. at 624 (Ellis) ("If it was 8(e) data that the agency determined . . . disrupted the agency's ability to

do something with it, it would be a per day penalty or the $62 million approach . . . .")) The TSCA ERP also allows for consideration of the type of information involved in a particular TSCA section 8(e) violation; under the ERP, violations involving human health data are treated more seriously than those involving animal data. CX 103 at 14, 25 [1999 TSCA ERP]; Tr. at 599 (Ellis); Compl't Initial Post-Hearing Brief at 51. Therefore, the proposed penalty calculation did consider the specific information contained in the Final Four Plant Report as well as the fact that EPA has not yet had the opportunity to use that information.

Second, Respondent argues that its failure to report was based on "a good-faith belief that the information was only corroborative" that EPA should have taken into account in the proposed penalty calculation. (Resp't Initial Post-Hearing Brief at 48.) In support of this argument, Respondent notes that no evidence was presented at hearing to indicate "that Elementis intended to hide the Final Four Plant Report from EPA or anyone else." Id. at 49. Although Respondent's overall argument is based on the statutory factor of "other matters as justice may require," the points it makes in support of its second argument are most applicable to the "degree of culpability" factor. (See Resp't Initial Post-Hearing Brief at 48; see also 15 U.S.C. § 2615(a)(2)(B).) As discussed in Complainant's Initial Post-Hearing Brief, Complainant did consider Respondent's culpability when calculating the proposed penalty. (See Compl't Initial Post-Hearing Brief at 53-54.)

Respondent's argument that "Dr. Barnhart decided against providing the Final Four Plant Report to EPA pursuant to a good faith interpretation of the statute and EPA's policy and guidance documents" is contrary to Dr. Barnhart's own testimony. (See Resp't Post-Hearing Brief at 49-50.) At hearing, Dr. Barnhart testified: "I don't know that I had actually ever read 8(e) or the guidance but I understood that if something new came out that was significant,

showing an adverse effect that was especially unexpected or much greater than expected, that there was a reporting requirement for it." (Tr. at 990-91 (Barnhart).) While Dr. Barnhart may have felt he acted in good-faith in deciding not to report the Final Four Plant Report, his decision apparently was not based on his "interpretation" of the statute or guidance. In fact, as discussed in Complainant's Initial Post-Hearing Brief, Dr. Barnhart had a significant misunderstanding of the reporting requirement which could have been clarified had he asked the Agency at the time. (See Compl't Post-Hearing Brief at 54 n.18; see also Tr. at 51-52, 60 (Krasnic); CX 21 at 3-7 [1991 Reporting Guide] (list of contact information).)

Furthermore, the Guidelines for the Assessment of Civil Penalties Under Section 16 of the Toxic Substances Control Act; PCB Penalty Policy ("Guidelines") provide that a level 1 culpability violation, where the violation was willfully or intentionally committed, allows for a 25% increase in the gravity-based penalty. CX 102 at 5 [Guidelines]. Although Dr. Mundt mentioned a third party accusation, Respondent is correct that EPA did not put forth any evidence to suggest that Respondent "intended to hide the Final Four Plant Report from EPA . . . ." (See Tr. at 932-936 (Mundt).) If EPA had such evidence the penalty likely would have been adjusted upward by 25%. Instead, EPA found that Respondent's violation, in terms of culpability, was a level 2 violation which did not warrant either an upward or downward adjustment to the gravity-based penalty. See CX 102 at 5 [Guidelines].

Finally, Respondent argues that two other chromium chemical manufacturers allegedly also obtained and failed to submit the Final Four Plant Report to EPA. (Resp't Initial Post-Hearing Brief at 50.) As discussed in Complainant's Initial Post-Hearing Brief, each company had an independent obligation to report the information contained in the Final Four Plant Report unless that company had actual knowledge that the Administrator had already been adequately

informed of that information. Respondent has provided no evidence to show that it had reason to believe another company had reported the Final Four Plant Report to EPA. Thus, Respondent is fully responsible for the violation's occurrence and no reduction to the proposed penalty is warranted. See CX 102 at 5 [Guidelines] ("*Initial culpability determination:* . . . Level II: The violator either had sufficient knowledge to recognize the hazard created by his conduct, or significant control over the situation to avoid committing the violation. — No adjustment to the GBP.")

As discussed here and at length in Complainant's Initial Post-Hearing Brief, EPA has fully considered each of the statutory penalty factors and has determined that nothing in the facts or circumstances of this case justify deviating from the TSCA ERP or Guidelines.

III. CONCLUSION

EPA respectfully renews its request that an order be entered in Complainant's favor finding Respondent liable as a matter of law for its continuing violation of section 8(e) of TSCA and imposing a civil penalty in the amount of $2,338,000.

Respectfully submitted,

5/1/2012
Date

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